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Practitioner's Docket No. 2003-IP-011261U1P1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of Invention

OR

In re application of: Keith A. Frost, et al.

Application No.: 0 10/785,300

Group Art Unit: 3672

Filed: 2/24/2004

Examiner: unknown

For: ORTHOESTER COMPOSITIONS AND METHODS FOR REDUCING THE  
VISCOSITY OF VISCOSIFIED TREATMENT FLUIDS

Mail Stop Amendment

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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))

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\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office  
Action [6-3]—page 1 of 3)

**NOTE:** 37 C.F.R. 1.98(b):

- (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.
- (2) Each U.S. patent application publication listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.
- (3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.
- (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.
- (5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

**WARNING:** No extension of time can be had under 37 C.F.R. § 1.136 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).

**NOTE:** The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

**NOTE:** "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

**NOTE:** "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39). See also § 609, M.P.E.P., 8th Edition.

**NOTE:** "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

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PTO-1449  Information Disclosure Citation in an Application	Application No. 10785,300	Applicant(s): Keith A. Frost, et al.	
	Docket Number 2003-IP-011261U1P2	Group Art Unit 3672	Filing Date 02/24/2004

**U.S. PATENT DOCUMENTS**

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	5,607,905	03/04/97	Dobson, Jr. et al.	507	211	03/15/94
	6,394,185 B1	05/28/02	Constien	166	296	07/27/00
	6,761,218 B2	07/13/04	Nguyen et al.	166	278	04/01/02
	US 2002/0125012 A1	09/12/02	Dawson et al.	166	300	01/08/02

**NON-PATENT DOCUMENTS**

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
	SKRABAL ET AL., <i>THE HYDROLYSIS RATE OF ORTHOFORMIC ACID ETHYL ETHER</i> , CHEMICAL INSTITUTE OF THE UNIVERSITY OF GRAZ, PAGES 1-38	01/13/21
	Heller, et al., <i>Poly(ortho esters) – From Concept To Reality</i> , Biomacromolecules, Vol. 5, No. 5, 2004 (pp. 1625-1632)	05/09/79
	Schwach-Abdellaoui, et al., <i>Hydrolysis and Erosion Studies of Autocatalyzed Poly(ortho esters) Containing Lactoyl-Lactyl Acid Dimers</i> , American Chemical Society, Vol. 32, No. 2, 1999 (pp. 301-307)	
	Ng, et al., <i>Synthesis and Erosion Studies of Self-Catalyzed Poly(ortho ester)s</i> , American Chemical Society, Vol. 30, No. 4, 1997 (pp. 770-772)	
	Ng, et al., <i>Development Of A Poly(ortho ester) prototype With A Latent Acid In The Polymer Backbone For 5-fluorouracil Delivery</i> , Journal of Controlled Release 65 (2000), (pp. 367-374)	
	Rothen-Weinhold, et al., <i>Release of BSA from poly(ortho ester) extruded thin strands</i> , Journal of Controlled Release 71, 2001, (pp. 31-37)	
	Heller, et al., <i>Poly(ortho ester)s – their development and some recent applications</i> , European Journal of Pharmaceutics and Biopharmaceutics, 50, 2000, (pp. 121-128)	
	Heller, et al., <i>Poly(ortho esters); synthesis, characterization, properties and uses</i> , Advanced Drug Delivery Reviews, 54, 2002, (pp. 1015-1039)	
	Heller, et al., <i>Poly(ortho esters) For The Pulsed And Continuous Delivery of Peptides And Proteins</i> , Controlled Release and Biomedical Polymers Department, SRI International, (pp. 39-46)	
	Zignani, et al., <i>Subconjunctival biocompatibility of a viscous bioerodable poly(ortho ester)</i> , J. Biomed Mater Res, 39, 1998, pp. 277-285	
	Toncheva, et al., <i>Use of Block Copolymers of Poly(Ortho Esters) and Poly (Ethylene Glycol)</i> , Journal of Drug Targeting, 2003, Vol. 11(6), pp. 345-353	
	Schwach-Abdellaoui, et al., <i>Control of Molecular Weight For Auto-Catalyzed Poly(ortho ester) Obtained by Polycondensation Reaction</i> , International Journal of Polymer Anal. Charact., 7: 145-161, 2002, pp. 145-161	
	Heller, et al., <i>Release of Norethindrone from Poly(Ortho Esters)</i> , Polymer Engineering and Science, Mid-August, 1981, Vol. 21, No. 11 (pp. 727-731)	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.	